

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: Tomoki Kato :
APPLICATION NO.: 10/595,948 : Examiner: Scarlett Y. Goon
FILING DATE: May 22, 2006 : Group Art Unit: 1623
TITLE: Quinolonecarboxylic Acid Compounds Having : Confirmation No.: 9541
5-HT₄ Receptor Agonistic Activity

Hon. Commissioner for Patents
Via EFS

Sir:

DECLARATION UNDER 37 CFR 1.132

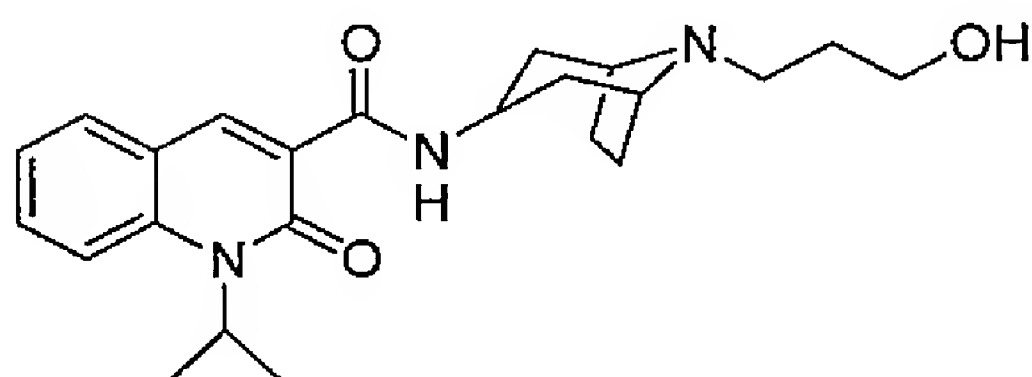
I, Kiyoshi Kawamura, declare that:

1. I was awarded a Master's Degree in organic chemistry in March 1994 by the Nagoya Institute of Technology. I was previously employed by Pfizer Japan Inc. from April 1994 to June 2008, my title being Senior Scientist. I am currently employed by RaQualia Pharma Inc., my title being Principal Scientist.
2. Pfizer Japan Inc. is owned by Pfizer Inc., the Assignee of the above-identified application.
3. I am familiar with the instant patent application in which I am an inventor. I have read the Office Action which bears a mailing date of July 21, 2009, and I am aware of the rejection of claims 15-20, 24 and 25 for obviousness over JP 09-194374 to Ouchi et al. in view of EP 0382687 to Micheletti et al. as set forth therein.
4. Under my supervision and guidance, the data in the following table was obtained in accordance with the procedure titled as "Human 5-HT₄ binding"

disclosed starting at page 19 and the procedure titled as “Human dofetilide binding” disclosed starting at page 22. Results are summarized as follows.

Compound	h5-HT ₄ (nM) (=A)	dofetilide (μM) (=B)	Therapeutic Index based on dofetilide/5-HT ₄ ratio (B/A)
Compound A	40.5	1.55	38
Example 2	6.17	1.9	308
Example 6	5.3	1.8	340
Example 7	5.24	5.83	1113
Example 8	5.2	5.35	1029
Example 11	7.56	6.61	874
Example 12	8.54	4.39	514

5. Compound A is the following compound,



which is Ouchi's compound as claimed in claim 2 of JP 09-194374.

6. The results presented above clearly demonstrate that the compounds of the instant invention generally possess a surprisingly superior Therapeutic Index (TI), and in addition possess greatly improved 5-HT₄ activity.

7. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that theses statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Respectfully submitted,

Dec 21, 2009

Date

Kiyoshi Kawamura

Kiyoshi Kawamura